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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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05/306,006 05/06/99 SUPERSAXO A NB/2-21551/A

000324 HM12/1219
CIBA SPECIALTY CHEMICALS CORPORATION
PATENT DEPARTMENT
540 WHITE PLAINS RD
P O BOX 2005
TARRYTOWN NY 10591-9005

EXAMINER

SHARAREH, S

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/306,006

Applicant(s)

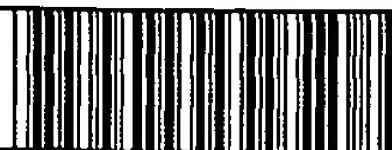
Supersaxo et al

Examiner

Shahnam Sharareh

Group Art Unit

1619



☒ Responsive to communication(s) filed on Oct 2, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2, 6, 10, 15-21, 24, 28, and 29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2, 6, 10, 15-21, 24, 28, and 29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Amendment filed on October 12, 2000 has been entered. Accordingly, claims 5, and 9 have been canceled, and claims 10, 28-29 have been amended. Claims 2, 6, 10, 15-21, 24, 28-29 are now pending. Applicant is informed that claim 12 was canceled on the amendment filed April 10, 2000, and is not pending.

Response to Amendment

1. Applicant's arguments with respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Mizushima et al U.S. Patent 5,171,566 have been fully considered and are found persuasive, because Mizushima does not teach compositions consisting essentially of a phospholipid, polyoxyethylene coemulsifier, triglyceride, a lipophilic drug in an ethanol based solvent system. Therefore, said rejection is withdrawn in view of the amendments made to the independent claims.
2. Applicant's arguments with respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Nakajima et al US Patent 5,338,761 have been fully considered and are found persuasive, because Nakajima et al do not teach compositions consisting essentially of a phospholipid, polyoxyethylene coemulsifier, triglyceride, a lipophilic drug in an ethanol based solvent system. Therefore, said rejection is withdrawn in view of the amendments made to the independent claims.
3. Applicant's arguments with respect to the rejection made under 35 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Owen et al US

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Patent 5,633,226 have been fully considered and are not persuasive, because Owen et al do not teach an aqueous nanodispersion of a lipophilic pharmaceutical active agent, consisting essentially of a phospholipid, polyoxyethylene coemulsifier, triglyceride, a lipophilic drug in an ethanol based solvent system. Said rejection is withdrawn.

4. Applicant's argument with respect to the rejection under 35 U.S.C. 102(b) as being anticipated by WO 95/16441 have been fully considered and are found persuasive, because of the '441 patent does not teach ethanol based micro emulsion systems. Said rejection is withdrawn.

New Grounds of rejection

5. Claims 2, 6, 10, 15-21, 24, 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Weder US Patent 5,997,888 in view of WO 96/37192 ('192).

The instant claims are aqueous nanodispersion formulations consisting essentially of (a) 0.1-30% by weight of phospholipid, (b) 1-50% by weight of polyoxyethylene coemulsifiers, (c) 0.1-80% by weight of a lipophilic component which is a natural or synthetic C4-C18 triglyceride and a lipophilic active agent, (d) 0.63-14.2% by weight ethanol and a water phase. The claims are also directed to methods of preparing said nanodispersion formulations.

Weder et al disclose cosmetic compositions containing nanodispersions comprising a fatty acid esters of polyoxyethylene sorbitans as emulsifying agent in amount of 0.1%-5%, at least one phospholipid in amount of 0.1%-5%, ethanol in amount of 0.65%, a water phase, and a lipophilic active agent such as tocopherol acetate, or vitamin A palmitate, *examples 1-5, claims 1-10.*

Weder et al also teach conventional mixing of their components utilizing a magnetic stirrer or a

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static mixer, *col 8 lines 1-5*. Weder further disclose that their mean particle size is about 50 nanometers, *col 8 lines 14-18*. Weder et al however fail to use a combination of triglycerides and the active lipophilic agents.

'192 patent is used to show that the use of triglycerides to improve stability and solubility of a lipophilic drug in an aqueous emulsion system is conventional, *entire document, claims 1-5*.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to further incorporate a triglyceride moiety with the lipophilic active agent of Weder, as taught in '192 patent, to improve stability and thus shelf half life of the nanodispersion of Weder. Furthermore, methods of preparing such dispersions would have also been routine and thus obvious.

Conclusion

6. No claims were allowed.

Applicant is recommended to change the recitation of "polyoxyethylene type" in claims 28-29 to "polyoxyethylene coemulsifiers" to better define the scope of the claims. Also, the prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hong et al US Patent 6,028,067 is not used, because it does not add any further teachings to the already cited prior arts. However, Applicant is encouraged to acknowledge and comment on this reference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because the scope of the independent claims have been modified. Accordingly, **THIS**

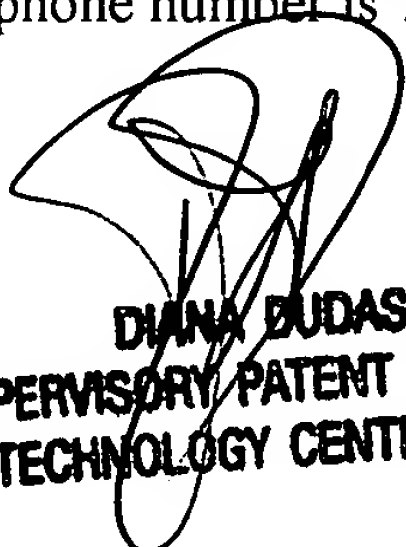
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ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs, 12/12/2000


**DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**